

(19)



Europäisches Patentamt
European Patent Office
Office européen des brevets



(11)

EP 0 910 421 B1

(12)

EUROPEAN PATENT SPECIFICATION

(45) Date of publication and mention
of the grant of the patent:
26.03.2003 Bulletin 2003/13

(51) Int Cl.7: **A61M 11/06, B05B 7/00**

(21) Application number: **97927296.0**

(86) International application number:
PCT/GB97/01682

(22) Date of filing: **20.06.1997**

(87) International publication number:
WO 97/048431 (24.12.1997 Gazette 1997/55)

(54) **DISPENSING SYSTEM**

**VERNEBLER MIT DOSIEREINRICHTUNG
SYSTEME DISTRIBUTEUR**

(84) Designated Contracting States:
**AT BE CH DE DK ES FI FR GB GR IE IT LI NL PT
SE**

- **DYCHE, Anthony**
Hampshire PO11 0ND (GB)
- **BASISTA, Jacek, Lech**
Kent TB4 9QT (GB)

(30) Priority: **20.06.1996 GB 9612968**

(43) Date of publication of application:
28.04.1999 Bulletin 1999/17

(74) Representative:
Wright, Howard Hugh Burnby et al
Withers & Rogers,
Goldings House,
2 Hays Lane
London SE1 2HW (GB)

(60) Divisional application:
02007007.4 / 1 245 244

(73) Proprietor: **Medic-Aid Limited**
Bognor Regis, West Sussex PO22 9SL (GB)

(56) References cited:
EP-A- 0 519 742 **WO-A-95/11714**
WO-A-96/13290 **GB-A- 1 568 808**
US-A- 3 658 059 **US-A- 4 558 710**

(72) Inventors:
• **DENYER, Jonathan, Stanley, Harold**
West Sussex PO21 3LQ (GB)

Note: Within nine months from the publication of the mention of the grant of the European patent, any person may give notice to the European Patent Office of opposition to the European patent granted. Notice of opposition shall be filed in a written reasoned statement. It shall not be deemed to have been filed until the opposition fee has been paid. (Art. 99(1) European Patent Convention).

EP 0 910 421 B1

Description

[0001] This invention relates to a dispensing system, in particular one which may be of use for example in the dispensing of small quantities of medicament, where the medicament is required to be dispensed in aerosol form.

[0002] It is known for dosing systems which supply a nebulized substance to containing a metering system. For example, in GB 1,568,808, (Rosenthal) there is described a metering system for supplying a nebulized substance for patient inhalation comprising a nebulizing means, a detecting means for detecting the initiation of the patient's inhalation, an adjustable timing means for adjusting a timed operation, and a valve means which is controlled by the timing means, in order to provide a controlled dosage of nebulized substance.

[0003] The preamble of claim 1 is based on the disclosure of said document.

[0004] However, for this system to work and provide a precise dose of medicament, it is necessary that the system utilises a calibrated nebulizer which has a precise rate of output against time. Commercially available nebulizers have a wide range of outputs against time. In addition, the calibration must remain constant over the use of the nebulizer, and the nebulizer must be connected to the dosing device in such a way that the calibration of the nebulizer is valid and recognised when operated with the dispensing device. This is particularly important in relation to the length of tube between the valve and the nebulizer.

[0005] Also, it is noted that this application describes no teaching of a device which is in any way calibrated for use with nominated drugs. This may have been due to the fact that the apparatus embodied in this application is designed for provocation testing, which is generally carried out in a laboratory, and is used to deliver pulses of aerosol into a patient's airway in order to determine their reactivity to allergens. The apparatus is not designed as one for a patient to take home, and to deliver precise doses of medicament on a day to day basis.

[0006] In addition to the above application, GB 2,164,569 (Etela-Hameen Kauhkovammayhdiatys RY (Finland)) describes a similar system to that described above, which is also designed for provocation testing, except that it has an additional atomizing starting time control, which is used for selecting the atomizing starting moment to coincide with the beginning of the inspiration phase, which is found by examination to be favourable for a particular patient.

[0007] EP 519,742 (DeVilbiss Healthcare Inc) describes a medical nebulizer control system which has a three way valve. In the embodiment, one part of the valve is connected to a pressure sensor, and another is connected to a compressed air supply. The control system within this apparatus uses the supply tube to the nebulizer to detect the patient's breathing pattern. When it detects inhalation, it switches the valve over to the compressed air supply, which then drives the nebulizer

for a predetermined period of time, irrespective of whether the patient has continued to inhale or not. This device also suffers from the problems of other nebulizers in that there is a long length of tube between the control box and the nebulizer. In addition the nebulizer can be supplied from any manufacturer, and hence its calibration is not tied into the device, thereby causing variable amounts of medicament to be dispensed.

[0008] According to the present invention, a product dispensing system comprises a calibrated nebulizer having a nebulizer jet, a mouthpiece, means for sourcing compressed air, a manifold for distributing the compressed air in at least one direction, a port, and a valve means for controlling the manifold and thereby the flow of compressed air to the port, the manifold and the port being linked by a length of tube, characterised by a nebulizer accommodation means which is accessed by the port, and in that the internal volume of the tube from the manifold outlet to the nebulizer jet is less than 0.7 ml.

[0009] Preferably, the internal volume of the tube from the manifold outlet to the nebulizer jet is less than 0.5 ml.

[0010] Conveniently, the dispensing system according to the invention is utilized in conjunction with a small air compressor as the source of compressed air, which has a flow rate in the region of 1-2 litres per minute

[0011] By "calibrated", in this instance, it is meant that the dosage rate for the nebulizer has already been established, and the dosimeter programmed accordingly, so as to provide a known dosage rate for a given medicament.

[0012] The dosage rate can be arranged to be fixed, regardless of the rate of inhalation of a patient, or variable depending on the rate of inhalation. What is important is that the dosage rate is known at a particular time. It is envisaged that a given dosimeter will have one or more dedicated nebulizers.

[0013] In preferred embodiments of the invention, the dispensing system additionally comprises a switch means, which is responsive as to whether compressed air is flowing in the system.

[0014] It is another preferred aspect of the invention that it may comprise a dispensing system comprising a dosimeter which has been pre-programmed to dose one or more medicaments according to predetermined dosage profiles.

[0015] The dispensing system according to the invention is conveniently one which is capable of being pre-programmed to dose one or more different types of drugs, which may need to be dosed according to different profiles. Methods of pre-programming the dispensing system in such a fashion will be familiar to those skilled in the art. In addition, the nebulizer and dosimeter according to the invention are calibrated to determine the dosage of drug as described in EP 587,380 (Medic-Aid Limited).

[0016] The dispensing system according to the invention incorporates a nebulizer and a mouthpiece, by which nebulized medicament can actually be delivered

to the patient. The dispensing system can also additionally preferably comprise a pressure sensor, which is capable in use of detecting a pressure drop in the apparatus in response to the patient's breathing, and then delivering a pulse of nebulized medicament into the mouthpiece. In such instances, the dose of medicament can be calculated by the known rate of output against time for the drug selected, and the sum of all nebulizer pulses which the system has delivered, in ways known to those skilled in the art, as referred to above. Such ways may typically include performing clinical trials on the drug to determine appropriate dosages, and programming these electronically into the dispensing system.

[0017] It is to be understood that the manifold in a dispensing apparatus according to the invention can, in fact, be an integral part of the valve means, and need not be a separately discreet entity. In certain embodiments, the manifold is a shaped block with internal galleys, for example, made of plastics materials, and its presence allows the tubes to be connected to the ports on the valve. The ports on the valve may be too close together to accommodate the connection of tubes directly, and a manifold increases the space between them in other embodiments it may be necessary for the manifold to distribute compressed air in at least two different directions.

[0018] The dispensing system according to the invention can operate from a variety of different compressed air sources, such as a continuous air supply at a rate of around 6 litres per minute. This can typically be provided either from a pressurized cylinder such as those used in hospitals, or can be generated from a conventional air compressor.

[0019] In an alternative and preferred configuration, the dispensing system can be operated with a lightweight compressor system, which typically generates a low flow rate (in the order of 1-2 litres per minute, preferably 1.5 litres per minute), in conjunction with an accumulator. Such a combination of low flow rate compressor and accumulator allows the dispensing system to produce pulses of compressed air to a nebulizer in the dispensing system with the flow around 6 litres per minute, where the flow from the compressor is matched to the mean flow through the nebulizer (1.5 litres per minute). In addition, such a combination of low flow rate compressor with accumulator, in conjunction with the dispensing system according to the invention, provides a dosing apparatus which is more lightweight, compact and readily portable than known dosing apparatuses.

[0020] With regard to the manifold, if the dispensing device according to the invention is used in conjunction with a low flow rate compressor, it is only necessary for the valve to switch the compressed air on and off to the nebulizer, in which case the manifold may only need to direct the compressed air in one direction only. However, if the dispensing system is used in conjunction with a conventional air supply such as a six litre per minute compressor or gas bottle supply, the manifold in con-

junction with the valve directs the flow to either the nebulizer or the outlet orifice. In such circumstances, the valve in conjunction with the manifold has either one port or two outlet ports, depending on the application.

[0021] An important feature of the dispensing systems according to the invention lies in the volume of the tube linking the manifold and the port being less than 0.7 ml, preferably less than 0.5 ml. It has been found that by using lengths of tube which have a relatively small volume, the nebulizer starts to work as quickly as possible once the patient's inhalation has been detected. Typically, it is possible that the nebulizer can work within 50 milliseconds of detecting the patient's inhalation. To facilitate both the rapid response time and the low volume of the tube linking the manifold and the port, it is preferred that the valve is physically close to the nebulizer.

[0022] If a relatively long tube, or one with a large internal volume is used between the manifold and the nebulizer, this tube has to be pressurized before the nebulizer starts to operate. This can have significant effects on the performance of the system with regard to the controlling the rate of output of the nebulizer, since the nebulizer should preferably be provided with an essentially constant rate ("square wave") of pressure over time, so that its output is constant over time. The nebulizer used in the dispensing system is preferably one which delivers inspiratory patterns between 0.1 and 1.5 seconds duration.

[0023] The invention will now be described further by way of example only with reference to the accompanying drawings, in which:

Figure 1 shows a schematic view of a dispensing system according to the invention, complete with a nebulizer and mouthpiece fitted;

Figure 2 shows a schematic cross-section view of the nebulizer/mouthpiece end of the dispensing system of Figure 1;

Figure 3 shows a further schematic cross-section view of the nebulizer/mouthpiece end of the dispensing system of Figure 1 from an orthogonal position to that shown in Figure 2;

Figure 4 shows a schematic cross-section view of the control system end of the dispensing system of Figure 1;

Figure 5 shows a schematic view of the dispensing system of Figure 1 attached to a low flow rate compressor;

Figure 6 shows a schematic representation of the combined dispensing system/compressor system of Figure 5;

Figure 7 shows a loading regime for loading an embodiment of dispensing system according to an aspect of the invention; and

Figure 8 shows cleaning regime for cleaning an embodiment of dispensing system according to an aspect of the invention.

Figure 9 shows an accumulator consisting of a generally hemispherical elastic diaphragm.

Figure 10 is a graph showing the nebulizer output rate of a typical nebulizer against the inspirator flow of a patient.

[0024] Referring to the figures, an embodiment of dispensing system according to the invention comprises a hand held dosimeter having a height of approximately 200 mm and a weight of approximately 200g. The dosimeter has a mouthpiece (1) and a nebulizer (2) attached, and a body (3) which contains a control valve, electronic circuitry and a battery. These components can be accessed through base (4).

[0025] The dosimeter is connected to a compressed air source via tube (10). To operate the dosimeter, the patient removes mouthpiece (1), and pours a liquid form of the medication (which be a liquid or a powder in a fluidised form, or any other similar form) into the nebulizer (2). Then, the dosimeter is connected to the compressed air supply via tube (10). By means of a switch device to be described later, the presence of a positive pressure in the dosimeter activates the control circuitry in the dosimeter, and switches it on.

[0026] In this embodiment, although the nebulizer has only one well in which the medication sits, the dosimeter is nevertheless pre-programmed to deliver the correct dose of two different nominated drugs. The dosimeter could, however, be constructed and pre-programmed so as to deliver any desired number of nominated drugs. The drug which has been loaded into the nebulizer is selected using selector buttons (5) and (6). Once the drug type is selected, LED's (7) and (8) indicate the drug type selected by the patient. Button (9) is a re-set button, so that the user can correct any errors in selection.

[0027] The nebulizer used in the dispensing system according to the invention can be any suitable nebulizer design with a known calibration constant which is used to nebulize substances such as medicaments, which is suitably adapted to fit the dispensing system, and calibrated with the dosimeter. Suitable nebulizers include those which use a source of compressed air to nebulize the medicament, and are, for example, described in European Patent No. 672,266 (Medic-Aid Limited). This patent discloses a reservoir through which a gas duct passes up through the centre. The liquid medication is held in the reservoir prior to atomisation. The gas duct terminates in a head having a single gas jet outlet and an adjacent medication outlet. A gas deflector is located

across and in the path of the gas issuing from the gas jet so that the gas is deflected sideways across the medication outlet. This generates a negative pressure above the medication outlet which draws medication from the reservoir below and atomizes it.

[0028] When the drug has been selected, the patient breathes in through mouthpiece (1). A pressure sensor (to be further described later) within body (3) detects a pressure drop within the mouthpiece (1) due to the patient's inhalation, and then delivers a pre-programmed pulse of nebulized medicament into the first 50% of the inspiratory profile, until the dose regime programmed into the dispensing system has been delivered.

[0029] The dose is calculated from a known rate of output against time for the drug selected, and the sum of all the nebulizer pulses which the dosimeter has delivered. Further information on how the doses of drug may be derived and pre-programmed into the dosimeter may be obtained from GB 2,294,402 (Medic-Aid Limited et al). This discloses an apparatus for administering a fluid medicament to a patient in a gas for inhalation, and for calculating the dosage administered to the patient comprising a holding chamber for temporarily holding the medicament and gas prior to inhalation and means for introducing a quantity of the medicament into the holding chamber. It includes a sensor for sensing the introduction of the medicament into holding chamber and a detector means for detecting the rate of flow of gas inhaled by a patient from the holding chamber. Calculation means calculate the amount of medicament received by a patient on the basis of several factors, including the preset quantity of medicament released into the holding chamber, the preset volume of the holding chamber, the time elapsed from the sensing of the introduction of the medicament and the detected rate of flow of gas inhaled from the holding chamber. The calculation takes account of the changing concentration of the medicament over time due at least in part to the deposition of the medicament within the holding chamber. In this instance, clinical trials have been conducted to determine the dose of drug that must be delivered to achieve the correct therapeutic effect, and this dose has been programmed into the dosimeter for the two nominated drugs.

[0030] When the programmed dose has been delivered, the LED adjacent the button relating to the selected drug flashes rapidly and a buzzer sounds, indicating that the treatment is finished, and thereby ensuring that a precise dosage of drug is delivered to the patient on every occasion.

[0031] The nebulizer used in this embodiment is shown in more detail in Figures 2 and 3. Compressed air is supplied via port (17) to the nebulizer jet (11), and this works in conjunction with baffle (12) to aerosolize the liquid drug which has been placed in nebulizer bowl (19).

[0032] This nebulizer is venturi nebulizer which draws in air through the spout (13) into the centre of the baffle

(12), and then up and out through the outlet of the spout (13) into the mouthpiece. As the nebulizer only generates aerosol during inspiration, the patient's inhaled air is drawn through valve (14), and further through the mouthpiece to the patient. A small proportion of this air is drawn down through the centre of the nebulizer to operate the venturi system. The flow through the nebulizer is completely independent of the patient's flow, and the nebulizer produces a constant rate of output. Valve (14) creates a pressure drop within the mouthpiece, and this is monitored through port (18). On exhalation valve (14) will close, and the patient will exhale through valve (15). Further information as the nebulizer on the nebulizer is contained in EP 627,266 (Medic-Aid Limited).

[0033] The complete assembly is held in place by catch (16). When the lower end of the catch is displaced the mouthpiece can be removed. The top end of the catch can then be tilted down to release the nebulizer bowl assembly from the main dosimeter case (3). This allows the whole nebulizer unit to be removed after the treatment has been completed, and cleaned completely separate from the main dosimeter case. This is further graphically illustrated in Figures 7 and 8.

[0034] Figure 4 shows an internal section through the dosimeter, in particular showing the electronic configuration of the device. Air enters the dosimeter via tube (10) and through flexible tube (22) to the manifold (21) and onwards to valve (20). To determine whether there is pressure in the tube (22), it is configured around wall (28). When there is no pressure in the tube, the tube collapses. However, under pressure it expands, and moves lever (29) against switch (30), which switches the dosimeter on.

[0035] The dosimeter can be operated from various different compressed air sources; firstly it can use either a continuous air supply of approximately 6 litres per minute, generated from a conventional air compressor, or a compressed bottled gas supply such as is used in hospitals. With these compressed air sources, when the compressed air is not being supplied to the nebulizer via tube (23) and port (17), it must be vented externally through tube (24) out of the base of the dosimeter via an orifice which matches the size of the jet (11) diameter in the nebulizer. This maintains a constant pressure in the system irrespective of whether the valve is directing air to the nebulizer or the vent.

[0036] In an alternative and preferred embodiment, which can be used in conjunction with other forms of dosimeter, the dosimeter can be operated in conjunction with a low flow rate compressor system having a flow rate of 1-2 litres per minute, which has a fitted accumulator.

[0037] This compressor system generates a low flow of, for example, 1.5 litres per minute in the accumulator, and this allows the dosimeter to produce pulses of compressed air to the nebulizer with an equivalent flow rate of around 6 litres per minute, where the flow from the compressor is matched to the mean flow through the

nebulizer (1.5 litres per minute). In this configuration tube (24) is sealed, and when the valve (20) is closed the pressure in the supply tube (10) is diverted into the compressor's accumulator. Port (18) connects the pressure sensor (25) to the mouthpiece. This is attached to the printed circuit board (31) - which is powered by battery (26). When the electronic system detects the patient has inhaled, valve (20) diverts the pressure flow into tube (23) and out to a nebulizer via port (17). The battery is inserted into the dosimeter via door (27) into base (4).

[0038] An example of a suitable low flow rate compressor which can be used as described above is shown in Figures 5 and 6, and comprises a small air compressor with a flow of approximately 1.5 litres per minute, and an accumulator with a volume of about 0.2 litres, which may be formed, for example, in the tubing between the compressor and the dosimeter, or using a bellows and spring arrangement within the compressor casing. Below is described a rubber hemisphere accumulator which works particularly well. The compressor operates until the accumulator has reached its capacity, and then switches off. The dosimeter receives pulses of air from the accumulator until the accumulator has been emptied to a specified volume (0.1 litre). The compressor then cuts in and refills the accumulator. The compressor produces a mean output flow rate which is known to the dosimeter, and the dosimeter controls its supply of air so that it does not exceed the mean flow rate from the compressor, and any one pulse delivered by the dosimeter does not exceed accumulator capacity. This system therefore utilizes the compressor, which is approximately one-quarter of the size of a conventional compressor system, and one quarter of the energy requirement. Such a compressor is also cheaper to manufacture and provide.

[0039] The accumulator in this embodiment should have a linear pressure to volume relationship over the period of a pulse delivery, which is typically 1.5 seconds long, with a nebulizer jet flow of 6 litres per minute, the accumulator should provide a volume flow of 150 millilitres at a constant pressure (1bar +/- 10%). It is difficult to obtain a steady linear pressure to volume relationship. Figure 9 shows a natural rubber hemispherical accumulator. The rubber has a linear load to extension between an extension of 100% and 500%. A diaphragm 91 is a hemispherical component which is held trapped between two rings 92 and 93. In Figure 9, the diaphragm is shown in three positions labelled A, B, C. Position A is the unloaded position from which the diaphragm starts and as compressed air is supplied via a port 94, the diaphragm expands to position C with a 200% extension. The compressed air supply is then stopped either by the actuation of a microswitch on the diaphragm surface (not shown) which stops the compressors, or by a pneumatic microswitch which then vents the compressor output. The diaphragm 91 then stays in this position until the valve sends a pulse of air to the nebulizer. When the diaphragm delivers air, the pressure drop during opera-

tion is less than 5%. The diaphragm can supply air at a stable pressure until it reaches position B which is a 120% extension. The microswitch would then restart the compressor, or the pneumatic microswitch would be closed. This hemisphere arrangement is relatively simple to manufacture, but has great advantages over other accumulator systems which might be used.

[0040] A suitable electrical configuration for such a compressor is shown in Figure 6.

[0041] For the dispensing system according to the invention to work effectively, the dosimeter valve (20) should be in close proximity to the nebulizer, so that when the system detects the patient's inhalation, the nebulizer starts to work as quickly as possible, typically in less than 50 milliseconds. This means that the length of tube (23) between the manifold outlet and the nebulizer jet must be short, with an internal volume less than 0.7 ml, preferably less than 0.5 ml, which represents 5% of the shortest pulse the nebulizer delivers. If a long tube is used between the valve and the nebulizer, this tube has to be pressurized before the nebulizer starts to operate. This significantly affects the performance of the system, as to control the rate of output of the nebulizer it must be supplied with a "square wave" of air pressure, so that the output is constant over time, and is delivered at the start of inhalation. The nebulizer delivers pulses to inspiratory patterns between 0.1 and 1.5 seconds' duration.

[0042] One of the simplest ways of determining the dose of medicament which is received by the patient is, as described as above, to multiply the nebulizer output rate by the duration of each pulse. The doses then ascertained by summing the amount of medicament which is received during each pulse. This calculation relies on the fact that the output rate of a nebulizer should be constant regardless of the rate of inhalation of the patient. Therefore, provided that the nebulizer output rate is the same for a person who inhales slowly as for a patient who inhales quickly, the calculation will be accurate. If the nebulizer output rate varies with the speed of inhalation, the precision of the dosimeter will vary.

[0043] Figure 10 is a graph showing the variation of aerosol output rate with the speed of inspiratory flow for a typical nebulizer. As will be seen, the output is not constant.

[0044] It is therefore proposed to use the pressure sensor to provide information on the patient flow rate so that the correct nebulizer calibration rate is determined during patient inhalation. This may be done in the form of a look-up table which is quite effective, and the look-up table can have two or more calibration points as required to provide the necessary accuracy. A satisfactory look-up table can be achieved by using an approximation of the look-up table which, in the case of the graph shown in Figure 10 can be made up of two straight lines, one line generally following the curve to the 30 lpm point and a second line which generally follows the curve above that. Such an approximation works well because,

in reality, the breathing pattern of a patient is not at a fixed level, but is continually changing.

[0045] Another way of using the correct calibration value is to use the computer which takes the inspiratory flow rate into account. One calibration value can be used above the 30 litres per minute level, and when the flow is below about 15 litres per minute, then the calibration constant is reduced to 60% of that value. Thus, the calibration may be achieved in a number of different ways not just a multi-point look-up table.

Claims

1. A product dispensing system comprising a calibrated nebulizer (2) having a nebulizer jet (11), a mouthpiece (1), means (10, 22) for sourcing compressed air, a manifold (21) for distributing the compressed air in at least one direction, a port (17), and a valve means (20) for controlling the manifold (21) and thereby the flow of compressed air to the port (17), the manifold (21) and the port (17) being linked by a length of tube (23), characterised by a nebulizer accommodation means which is accessed by the port (17), and in that the internal volume of the tube (23) from the manifold outlet to the nebulizer jet (11) is less than 0.7 ml.
2. A dispensing system as claimed in claim 1, pre-programmed to dose one or more medicaments according to predetermined dosage profiles.
3. A dispensing system as claimed in claim 1 or claim 2, wherein the manifold (21) is integral with the valve means (20).
4. A dispensing system as claimed in any one of claims 1 to 3, additionally comprising a compressor having a flow rate of 1-2 litres per minute and an accumulator (90).
5. A dispensing system as claimed in any one of claims 1 to 4, additionally comprising a switch means (30) which is responsive as to whether compressed air is flowing in the system.
6. A dispensing system as claimed in any one of the preceding claims, further comprising a dosimeter which has been pre-programmed to dose one or more medicaments according to predetermined dosage profiles.
7. A dispensing system according to any preceding claim, further comprising a pressure sensor (25) which is capable, in use, of detecting a pressure drop in the apparatus in response to the patient's breathing, whereby a pulse of nebulised medicament may be delivered into the mouthpiece (1).

8. A dispensing system according to claim 7 further comprising means for calculating the dosage of medicament on the basis of the known rate of medicament output against time for the selected drug.
9. A dispensing system according to any one of claims 1 to 6, further comprising a pressure sensor for detecting the rate of inhalation of air through the apparatus and means for calculating the dosage of medicament delivered on the basis of the detected rate of inhalation over time.
10. A dispensing system according to claim 8 or claim 9, further comprising an indicator arranged to indicate when a treatment is complete.
11. A dispensing system according to claim 10, further comprising means for determining when a pre-set dose has been delivered and for controlling the indicator.
12. A dispensing system according to any preceding claim, wherein the manifold (21) is an integral part of the valve means (20).
13. A dispensing system according to any one of the preceding claims, where the manifold (21) is a shaped block with integral galleys the presence of which allows the tubes to be connected to the ports on the valve.
14. A dispensing system according to any one of the preceding claims, further comprising a lightweight compressor system and an accumulator (90).
15. A dispensing system according to claim 14, wherein the lightweight compressor generates a low flow rate of the order of 1 to 2 litres per minute.
16. A dispensing system according to claim 14 or 15, wherein the combination of the low flow rate compressor and the accumulator (90) allows the dispensing system to produce pulses of compressed air to the nebuliser (2) with a flow of around of 6 litres per minute.
17. A dispensing system according to any one of claims 14-16, wherein the valve means (20) serves to switch the compressed air on and off.
18. A dispensing system according to any one of claims 1-12, wherein the manifold (21) together with the valve means (20) serve to direct the flow of compressed air either to the nebuliser (2) or to an outlet orifice.
19. A dispensing system according to any one of the preceding claims, wherein the volume of the tube

(23) linking the manifold outlet to the nebuliser jet (11) is less than 0.5 ml.

20. A dispensing system according to any one of the preceding claims, wherein the nebuliser (2) serves to deliver inspiratory pulses between 0.1 and 1.5 seconds in duration.
21. A dispensing system according to any one of claims 14 to 20, wherein the accumulator (90) includes a resilient elastic body (91) having a generally linear pressure to volume relationship.
22. A dispensing system according to claim 21, wherein the resilient body (91) is a generally hemispherical resilient element.
23. A dispensing system according to claim 21 or claim 22, wherein the hemispherical element (91) is a diaphragm extendable to 500% of its unloaded volume.

Patentansprüche

1. Ein System zum Abgeben eines Produktes, mit einem kalibrierten Vernebler (2) mit einer Verneblerdüse (11), einem Mundstück (1), Vorrichtungen (10, 20) zur Zufuhr von Druckluft, einem Verteiler (21) zum Verteilen der Druckluft in wenigstens eine Richtung, einem Anschluss (17) und einer Ventilvorrichtung (20) zur Steuerung des Verteilers (21) und hierdurch der Strömung der Druckluft zu dem Anschluss (17), wobei der Verteiler (21) und der Anschluss (17) über einen Längenabschnitt einer Röhre (23) verbunden sind, **gekennzeichnet durch** eine Vernebleraufnahmevorrichtung, welche unter Zugriff **durch** den Anschluss (17) steht, wobei das Innenvolumen der Röhre (23) von dem Verteilerauslass zu der Verneblerdüse (11) geringer als 0,7 ml ist.
2. Ein Abgabesystem nach Anspruch 1, welches vorprogrammiert ist, um eines oder mehrere Medikamente abhängig von bestimmten Dosierungsprofilen zu dosieren.
3. Ein Abgabesystem nach Anspruch 1 oder 2, wobei der Verteiler (21) einstückig mit der Ventilvorrichtung (20) ist.
4. Ein Abgabesystem nach einem der Ansprüche 1 bis 3, zusätzlich mit einem Kompressor mit einer Strömungsrate von 1 bis 2 l/min und einem Sammler (90).
5. Ein Abgabesystem nach einem der Ansprüche 1 bis 4, zusätzlich mit einer Schaltvorrichtung (30), wel-

che anspricht daraufhin, ob Druckluft in dem System fließt.

6. Ein Abgabesystem nach einem der voranstehenden Ansprüche, weiterhin mit einem Dosimeter, welches vorprogrammiert worden ist, um eines oder mehrere Medikamente abhängig von einem bestimmten Dosierungsprofil zu dosieren. 5
7. Ein Abgabesystem nach einem der vorhergehenden Ansprüche, weiterhin mit einem Drucksensor (25), der im Gebrauch in der Lage ist, einen Druckabfall in der Vorrichtung in Antwort auf die Atmung des Patienten zu erfassen, wodurch ein Stoß von vernebeltem Medikament in das Mundstück (1) lieferbar ist. 10
8. Ein Abgabesystem nach Anspruch 7, weiterhin mit einer Vorrichtung zur Berechnung der Medikamentendosierung auf der Basis der bekannten Rate eines Medikamentenausgangs gegenüber der Zeit für die ausgewählte Medizin. 15
9. Ein Abgabesystem nach einem der Ansprüche 1 bis 6, weiterhin mit einem Drucksensor zur Erkennung der Inhalationsrate von Luft durch die Vorrichtung und mit einer Vorrichtung zur Berechnung der Medikamentendosierung, welche zuzuführen ist, auf der Grundlage der erkannten Inhalationsrate über die Zeit hinweg. 20
10. Ein Abgabesystem nach Anspruch 8 oder 9, weiterhin mit einer Anzeige, die angeordnet ist, um anzuzeigen, wenn eine Behandlung abgeschlossen ist. 25
11. Ein Abgabesystem nach Anspruch 10, weiterhin mit einer Vorrichtung zum Bestimmen, wann eine vorab eingestellte Dosis verabreicht wurde und zur Steuerung der Anzeige. 30
12. Ein Abgabesystem nach einem der vorhergehenden Ansprüche, wobei der Verteiler (21) ein einstückiges Teil der Ventilvorrichtung (20) ist. 35
13. Eine Abgabevorrichtung nach einem der vorhergehenden Ansprüche, wobei der Verteiler (21) ein ausgeformter Block mit einstückigen Zügen ist, deren Vorhandensein erlaubt, dass die Leitungen mit den Anschlüssen an dem Ventil verbindbar sind. 40
14. Ein Abgabesystem nach einem der vorhergehenden Ansprüche, weiterhin mit einem leichtgewichtigen Kompressorsystem und einem Sammler (90). 45
15. Ein Abgabesystem nach Anspruch 14, wobei der leichtgewichtige Kompressor eine Strömungsrate in der Größenordnung von 1 bis 2 l/min erzeugt. 50

16. Ein Abgabesystem nach Anspruch 14 oder 15, wobei die Kombination aus dem Kompressor mit niedriger Strömungsrate und dem Sammler (90) es dem Abgabesystem ermöglicht, Impulse von Druckluft an den Vernebler (2) mit einer Strömung von ungefähr 6 l/min zu erzeugen.

17. Ein Abgabesystem nach einem der Ansprüche 14 bis 16, wobei die Ventilvorrichtung (20) dazu dient, die Druckluft ein- und auszuschalten.

18. Ein Abgabesystem nach einem der Ansprüche 1 bis 12, wobei der Verteiler (21) zusammen mit der Ventilvorrichtung (20) dazu dient, die Strömung von Druckluft entweder dem Vernebler (2) oder einer Auslassöffnung zuzuführen.

19. Ein Abgabesystem nach einem der vorhergehenden Ansprüche, wobei das Volumen der Röhre (23), welche den Verteilerauslass mit der Verneblungsdüse (11) verbindet, kleiner als 0,5 ml ist.

20. Ein Abgabesystem nach einem der vorhergehenden Ansprüche, wobei der Vernebler (2) dazu dient, Beatmungspulse zwischen 0,1 und 1,5 Sekunden lang zu liefern.

21. Ein Abgabesystem nach einem der Ansprüche 14 bis 20, wobei der Sammler (90) einen elastisch nachgiebigen Körper (91) beinhaltet, der eine im wesentlichen lineare Beziehung von Druck zu Volumen hat.

22. Ein Abgabesystem nach Anspruch 21, wobei der nachgiebige Körper (91) ein im wesentlichen halbkugelförmiges elastisches Element ist.

23. Ein Abgabesystem nach Anspruch 21 oder 22, wobei das halbkugelförmige Element (91) eine Membran ist, welche auf 500% ihres unbelasteten Volumens ausdehnbar ist.

Revendications

1. Système distributeur de produits, comprenant un nébuliseur étalonné (2) muni d'un ajutage de nébuliseur (11), une embouchure (1), des moyens (10, 22) destinés à servir de source d'air comprimé, une tubulure (21) destinée à distribuer l'air comprimé dans au moins une direction, un port (17), et un moyen de vanne (20) pour contrôler la tubulure (21) et donc le débit d'air comprimé arrivant au port (17), la tubulure (21) et le port (17) étant reliés par une certaine longueur de tube (23), **caractérisé en ce que** un moyen d'adaptation de nébuliseur permet d'accéder par le port (17) et le volume intérieur du tube

- (23) entre la sortie de la tubulure et l'ajutage de nébuliseur (11), est inférieur à 0,7 ml.
2. Système distributeur selon la revendication 1, **caractérisé en ce qu'**
il est programmé pour doser un ou plusieurs médicaments suivant des profils de dosage prédéterminés.
 3. Système distributeur selon la revendication 1 ou 2, dans lequel
la tubulure (21) fait partie intégrante du moyen de vanne (20).
 4. Système distributeur selon l'une quelconque des revendications 1 à 3, comprenant en outre
un compresseur ayant un débit de 1-2 litres par minute, et un accumulateur (90).
 5. Système distributeur selon l'une quelconque des revendications 1 à 4, comprenant en outre
un commutateur (30) répondant au fait que de l'air comprimé s'écoule dans le système.
 6. Système distributeur selon l'une quelconque des revendications précédentes, comprenant en outre
un dosimètre qui a été préprogrammé pour doser un ou plusieurs médicaments suivant des profils de dosage prédéterminés.
 7. Système distributeur selon l'une quelconque des revendications précédentes, comprenant en outre
un capteur de pression (25) capable de détecter, en cours d'utilisation, une chute de pression dans l'appareil en réponse à la respiration du patient, de façon qu'une impulsion de médicament nébulisé puisse être délivrée dans l'embouchure (1).
 8. Système distributeur selon la revendication 7, comprenant en outre
des moyens pour calculer le dosage de médicament sur la base du débit de sortie de médicament connu en fonction du temps, pour le produit pharmaceutique sélectionné.
 9. Système distributeur selon l'une quelconque des revendications 1 à 6, comprenant en outre
un capteur de pression pour détecter le taux d'inhalation d'air à travers l'appareil, et des moyens pour calculer le dosage de médicament délivré, sur la base du taux d'inhalation détecté au cours du temps.
 10. Système distributeur selon la revendication 8 ou 9,
- comprenant en outre
un indicateur disposé pour indiquer quand un traitement est terminé.
11. Système distributeur selon la revendication 10, comprenant en outre
des moyens pour déterminer le moment où une dose préréglée a été délivrée, et pour contrôler l'indicateur.
 12. Système distributeur selon l'une quelconque des revendications précédentes, dans lequel
la tubulure (21) fait partie intégrante du moyen de vanne (20).
 13. Système distributeur selon l'une quelconque des revendications précédentes, dans lequel
la tubulure (21) est un bloc mis en forme comportant des galeries intégrées dont la présence permet aux tubes d'être connectés aux ports de la vanne.
 14. Système distributeur selon l'une quelconque des revendications précédentes, comprenant en outre
un système de compresseur léger et un accumulateur (90).
 15. Système distributeur selon la revendication 14, dans lequel
le compresseur léger génère un débit faible de l'ordre de 1 à 2 litres par minute.
 16. Système distributeur selon la revendication 14 ou 15, dans lequel
la combinaison du compresseur à faible débit et de l'accumulateur (90) permet au système distributeur de produire des impulsions d'air comprimé allant vers le nébuliseur (2) avec un débit de l'ordre de 6 litres par minute.
 17. Système distributeur selon l'une quelconque des revendications 14 à 16, dans lequel
le moyen de vanne (20) sert à commuter l'air comprimé en marche/arrêt.
 18. Système distributeur selon l'une quelconque des revendications 1 à 12, dans lequel
la tubulure (21) associée à la vanne (20) sert à diriger le débit d'air comprimé soit vers le nébuliseur (2) soit vers un orifice de sortie.
 19. Système distributeur selon l'une quelconque des revendications précédentes,

dans lequel
le volume du tube (23) reliant la sortie de la tubulure
à l'ajutage de nébuliseur (11), est inférieur à 0,5 ml.

20. Système distributeur selon l'une quelconque des revendications précédentes, dans lequel le nébuliseur (2) sert à délivrer des impulsions d'inspiration d'une durée comprise entre 0,1 et 1,5 seconde. 5 10
21. Système distributeur selon l'une quelconque des revendications 14 à 20, dans lequel l'accumulateur (90) comprend un corps flexible élastique (91) ayant une relation de la pression au volume généralement linéaire. 15
22. Système distributeur selon la revendication 21, dans lequel le corps élastique (91) est un élément élastique généralement hémisphérique. 20
23. Système distributeur selon la revendication 21 ou 22, dans lequel l'élément hémisphérique (91) est un diaphragme extensible jusqu'à 500 % de son volume non chargé. 25 30

35

40

45

50

55

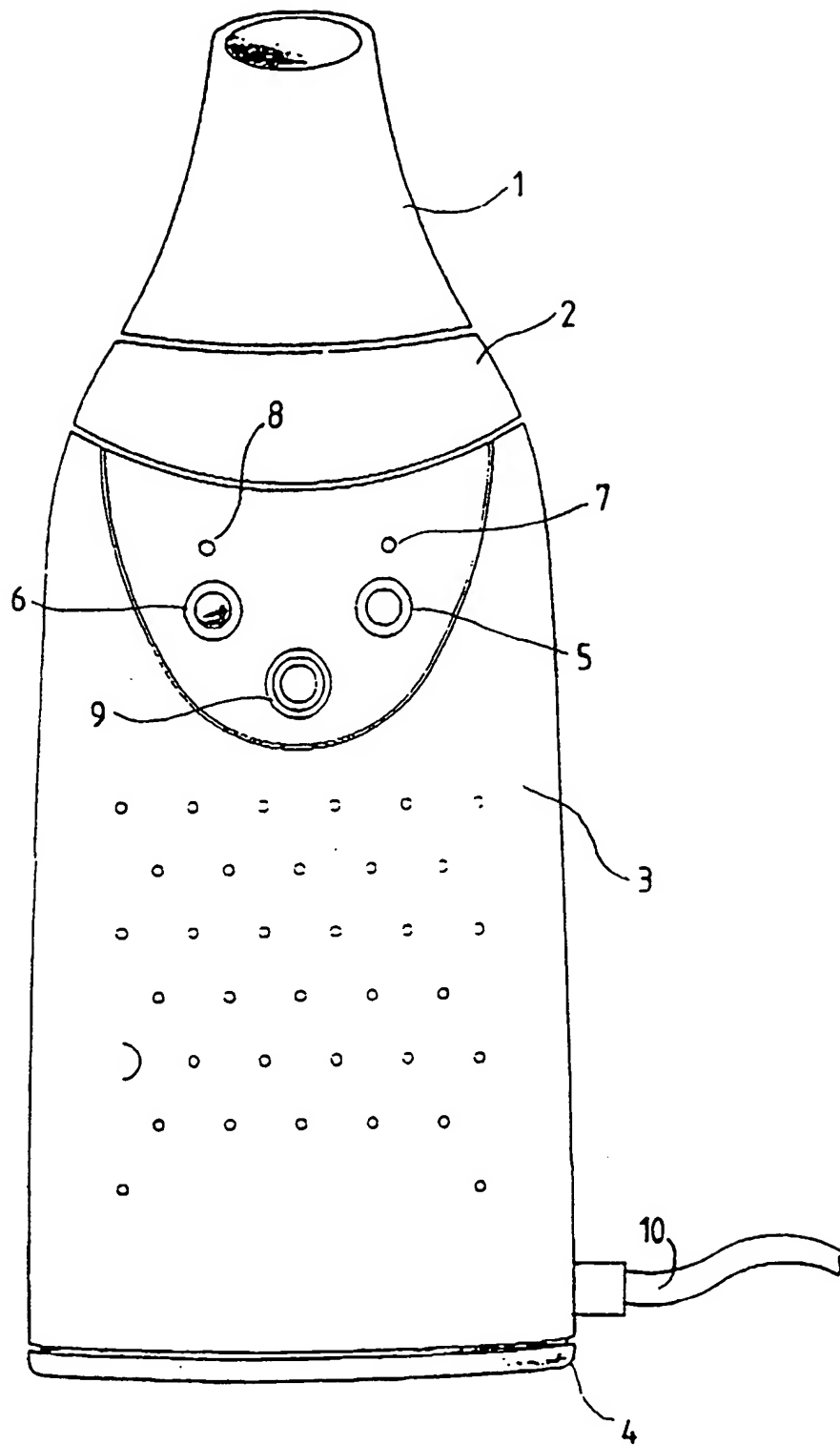


FIG.1

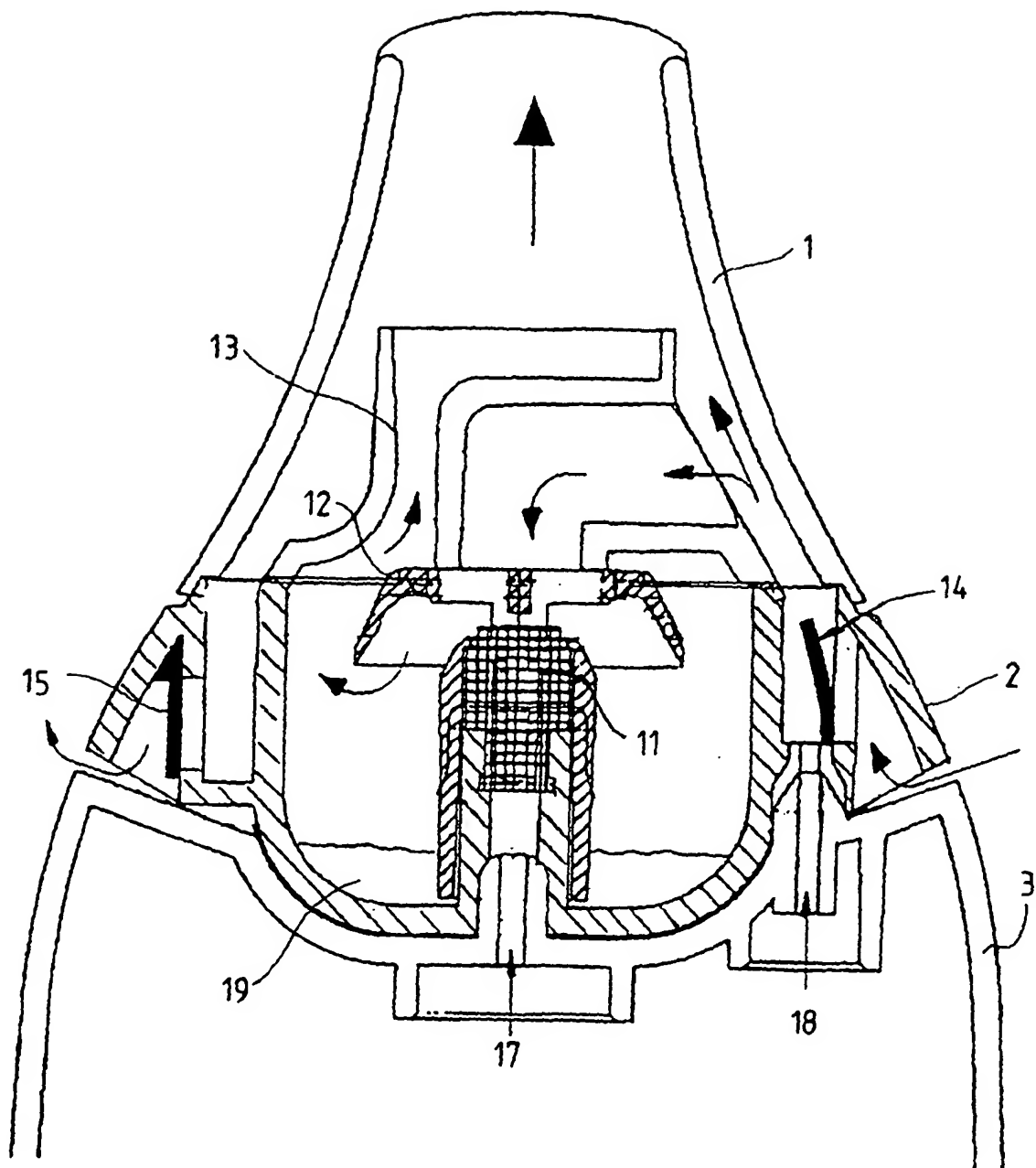


FIG.2

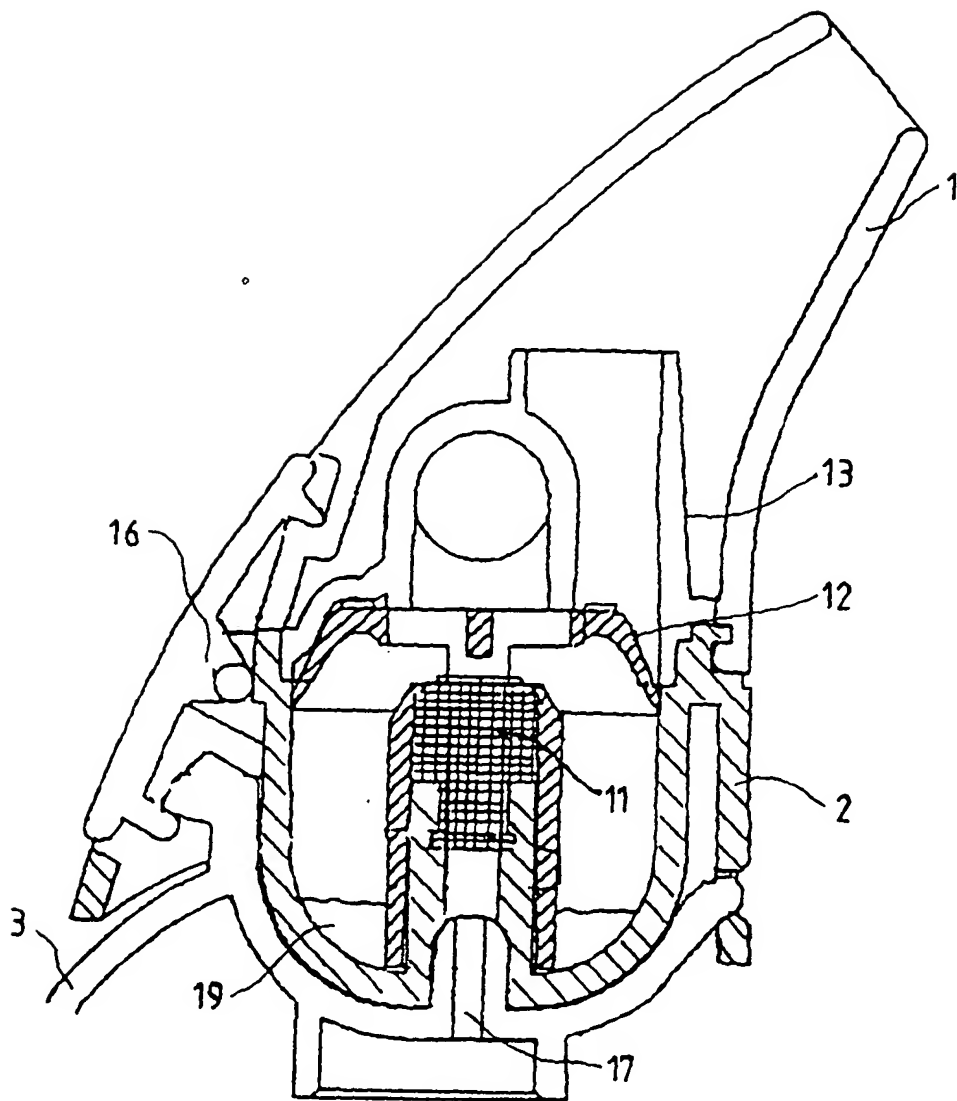


FIG. 3

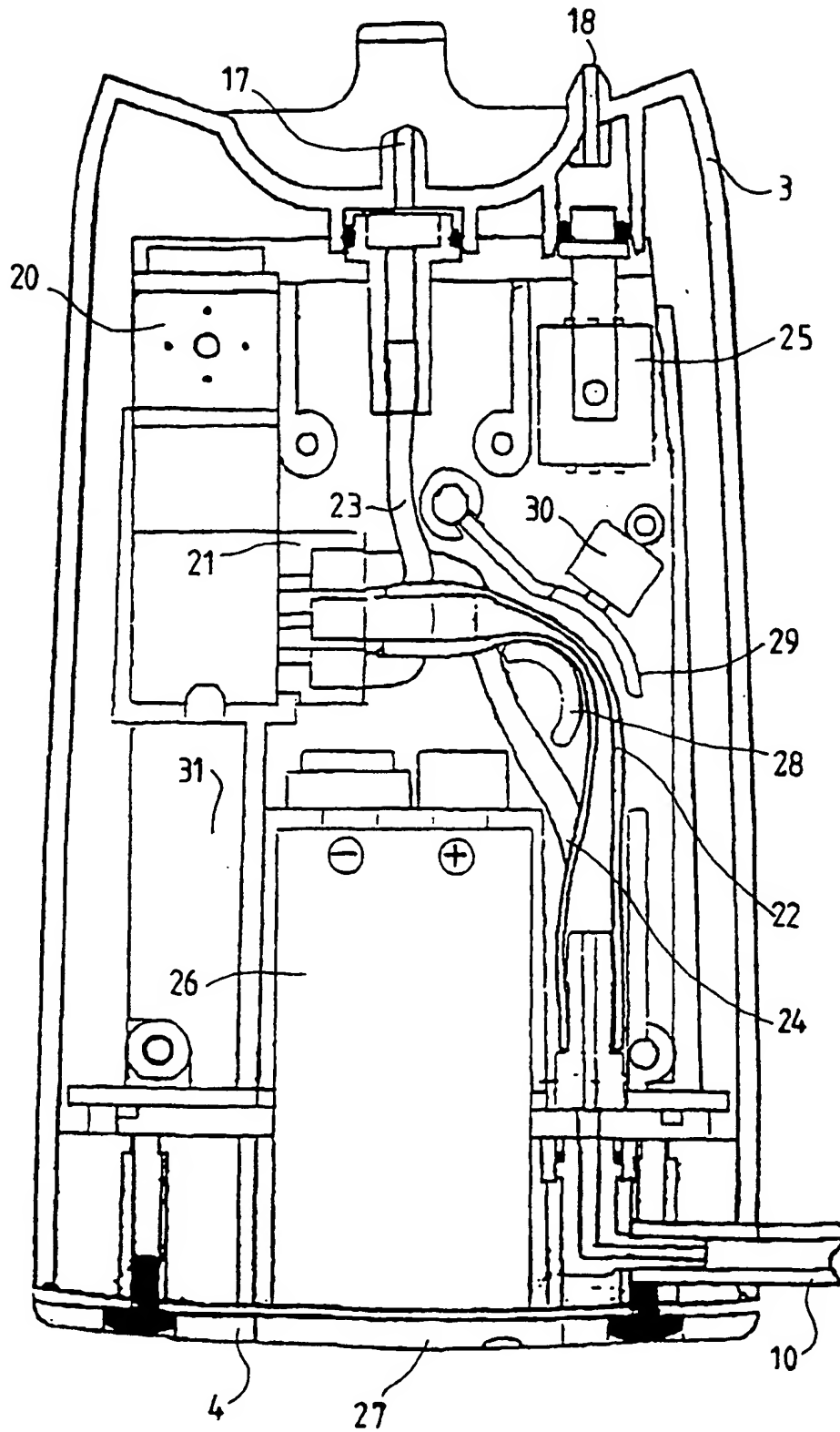


FIG. 4

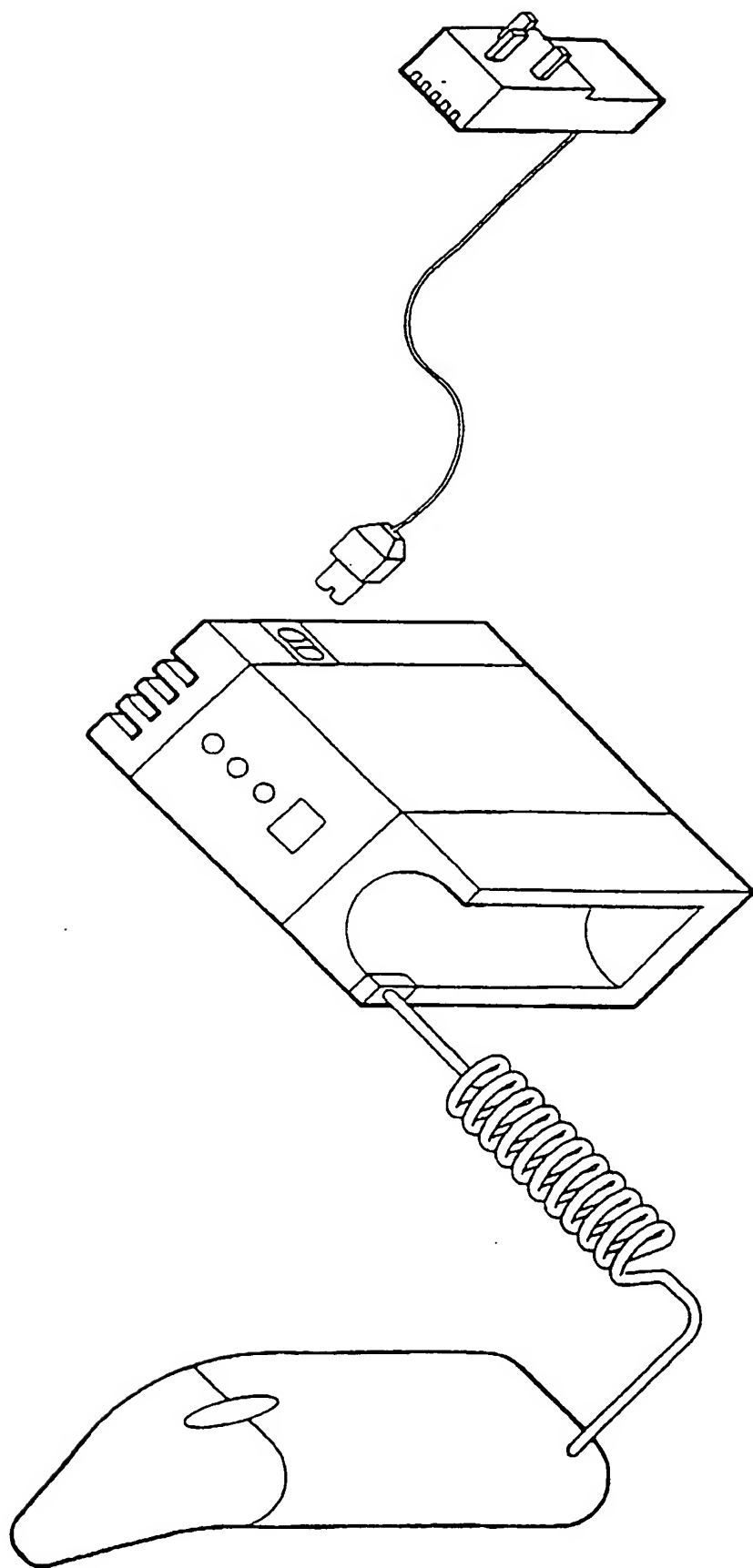


FIG. 5

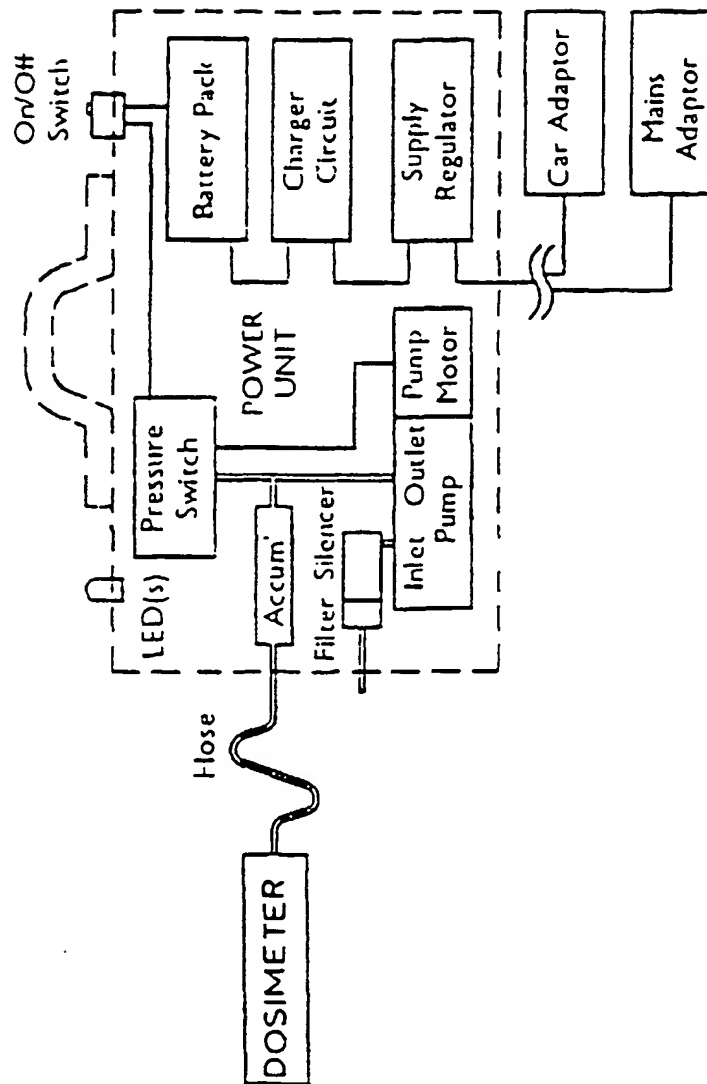
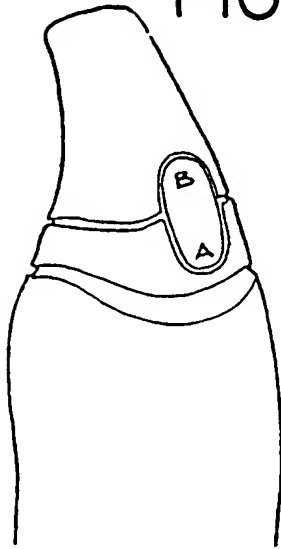


FIG. 6

TO LOAD

FIG 7a.



NEBULIZER CLEAN & EMPTY

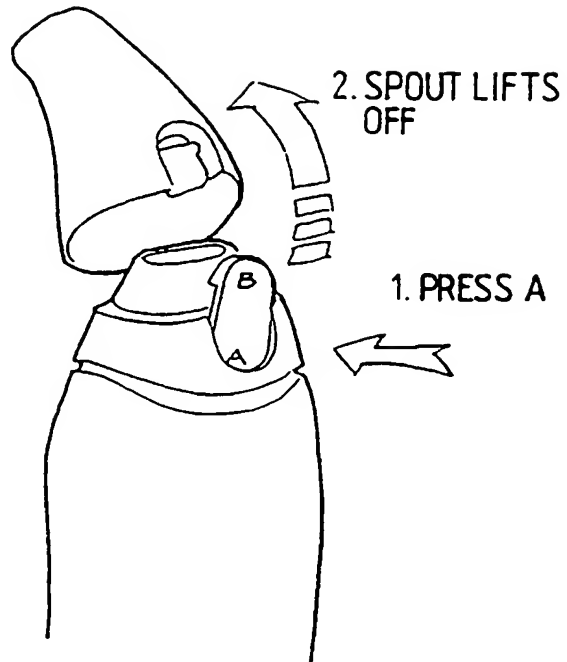
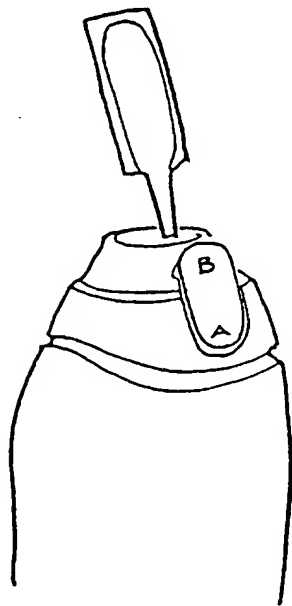


FIG.7b.



CHARGE THROUGH FUNNEL

FIG.7c.

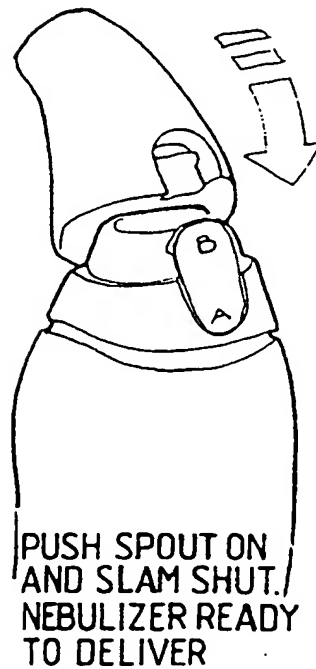


FIG.7d.

TO CLEAN

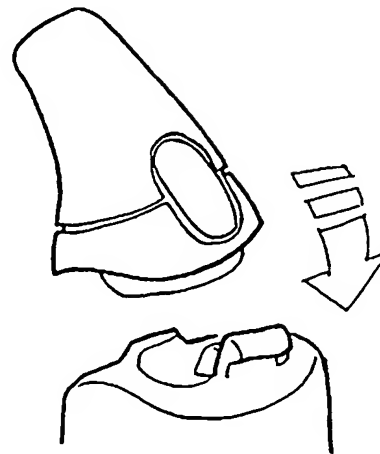


LIFT OUT FUNNEL



CLEAN & DRY
ALL PARTS
THEN EITHER...

REASSEMBLE BY STEPS
SHOWN IN FIGURES 8c,
8b, 8a IN REVERSE ORDER



B. SNAP COLLAR,
FUNNEL & SPOUT
TOGETHER
AS A UNIT
THEN SNAP UNIT
ONTO BODY

FIG. 8d.

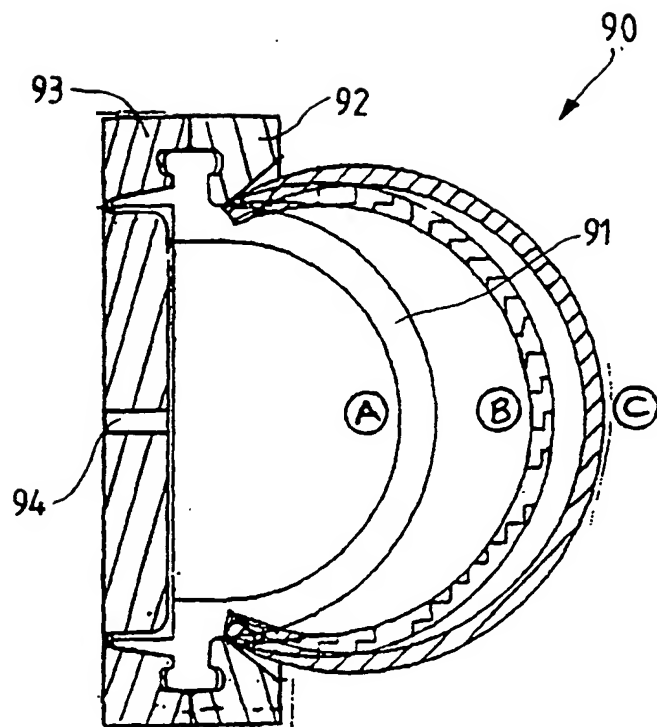


FIG.9

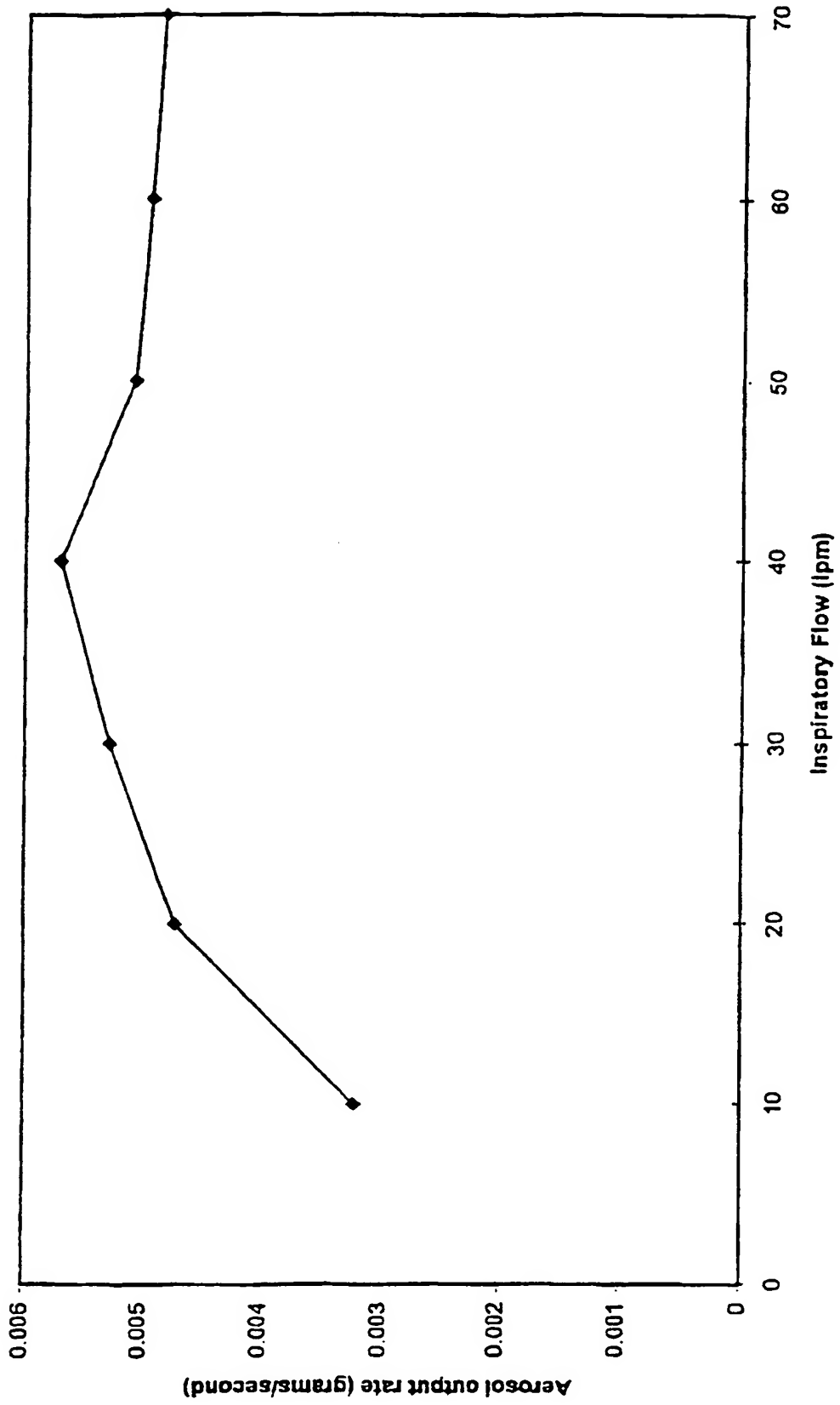


FIG.10